IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DOROTA ZYDEK **Plaintiff,** **v.** **AZIYO BIOLOGICS, INC., *et al.*,** **Defendants.**	**Case No. 23 C 3016** **Judge Harry D. Leinenweber**

MEMORANDUM OPINION AND ORDER

Defendants Aziyo Biologics, Inc. ("Aziyo"), Medtronic Sofamor Danek, USA, Inc., and Medtronic Sofamor's sole member SpinalGraft Technologies, LLC (collectively, "Medtronic") move to dismiss 12 counts of Plaintiff Dorota Zydek's 16-count Complaint under FED. R. CIV. PRO. 12(b)(6) for her purported failure to state a claim. (Dkt. No. 8.) These counts are as follows: Counts I, VI, and XI state claims based on strict products liability; and Counts II-IV, VII-IX, XII-XIV state claims based on Defendants' alleged breach of express, implied, and fitness warranties, respectively. For the reasons stated herein, Defendants' Motion to Dismiss is GRANTED.

I. BACKGROUND

Defendants Aziyo and Medtronic manufacture and produce a fiber-based surgical bone repair product called FiberCel. FiberCel is made from human tissue and engineered to maintain characteristics of natural tissue to facilitate bone repair and healing. To make FiberCel, Aziyo and Medtronic contract with Defendants DCI Donor Services, Inc. ("DCI"),

and New Mexico Donor Services, Inc. ("New Mexico Donor Services"), who locate, identify, test, and qualify parts of human cadavers for use in the development and manufacture of human products to be implanted into humans in surgical procedures. On April 15, 2021, Plaintiff Dorota Zydek underwent surgery to have FiberCel device VBM9910 implanted, which was made using human bone tissue from Donor Lot NMDS210011 ("Donor Lot"). A month later, on June 2, 2021, Aziyo voluntarily recalled FiberCels derived from this Donor Lot after seven of 23 patients implanted with that donor lot tested positive for tuberculosis. Zydek then received a letter advising her that the FiberCel she had implanted might have also been contaminated. On July 9, 2021, she was diagnosed with tuberculosis.

On May 12, 2023, Zydek sued Aziyo and Medtronic in Kane County Circuit Court for negligence, strict products liability, and breach of express, implied, and fitness warranty. Defendants then removed Zydek's Complaint to this Court based on diversity jurisdiction. 28 U.S. §§ 1332(a) & 1446(c). On May 19, 2023, Aziyo and Medtronic moved to dismiss Zydek's Complaint on all counts except for negligence, claiming that strict liability and contract-based claims are barred by Illinois's Blood and Organ Transaction Liability Act, 745 Ill. Comp. Stat. 40/01. The Court agrees with Defendants and grants Defendants' Motion to Dismiss.

II. LEGAL STANDARD

To survive a motion to dismiss for failure to state a claim, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007). This requires well-pleaded factual allegations that

"raise a right to relief above the speculative level." *Id.* "[L]egal conclusions" and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are insufficient. *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009). A claim is plausible only if the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*.

III. ANALYSIS

Illinois's Blood and Organ Transaction Liability Act ("the Act") expressly bars claims based on strict liability and warranty-breach for entities generally engaged in rendering services for blood- and human-tissue related surgeries. 745 Ill. Comp. Stat. § 40/1. Zydek argues that the Defendants' FiberCel falls outside the scope of the Act's liability limitation because the Act only applies to services or service providers, whereas the National Institute for Health ("NIH") and the Food and Drug Administration ("FDA") have labelled Defendants' FiberCel as a "product" in studies conducted on its efficacy.

How the NIH or FDA define a "product" is irrelevant to whether the FiberCel falls within "services" under the Act. "Services" (and service providers) as defined by the Act is a term of art provided by the Illinois legislature, which shields "every person, firm, or corporation" that participates in developing "blood products, blood derivatives and products, corneas, bones, or organs or other human tissue for the purpose of injecting, transfusing or transplanting any of them in the human body." *Id.* §§ 40/2-3. This is true "whether or not any remuneration is paid." *Id.* § 40/2. In *Brandt v. Boston Scientific Corp.,* the Illinois Supreme Court made clear that the Illinois legislature did not incorporate either of the NIH or FDA's definitions of "products." 204 Ill. 2d 640, 653

(2003). In fact, the *Brandt* court held that the defendant's ProteGen Sling ("the Sling") was predominately a "service" for purposes of liability under the Act because "the purchase of the sling was incidental to the" plaintiff's surgery – even though the NIH and FDA had identified the Sling as a "product." *Id.*; *See generally*, Carl Heneghan, *et al., Trials of Transvaginal Mesh Devices for Pelvic Organ Prolapse: a Systematic Database Review of the US FDA Approval Process,* PUB. NO. 10.1136, BMJ OPEN (2017). Hence, the surgical purpose of the Sling transformed what might ordinarily be considered a product into a legal service under the Act.

It is clear and straightforward that the Act applies to the FiberCel. First, there is no dispute that the FiberCel is "made from human tissue and engineered to maintain characteristics of natural tissue to facilitate bone repair and healing." (Compl. ¶ 4). Nor is it disputed that the Defendants "developed" the FiberCel, "which used human bone tissue . . . in whole or in part for use in one or more spinal surgical procedures." (*Id.* ¶ 5). Like the *Brandt* defendants, Aziyo and Medtronic's FiberCel was incidental to Zydek's surgery, and the device "was only potentially useful after its surgical implantation." 204 Ill. 2d at 652. As a result, Medtronic's FiberCel is characteristically a service under the Act, and, accordingly, Defendants are entitled to dismissal of Zydek's strict liability and warranty claims pursuant to the Act's liability limitation on these claims. *See also Gnutek v. DCI Donor Services Inc., et al.,* No. 22 L 002249 (Cir. Crt. Cook County 2022) (dismissing identical strict liability and breach of warranty claims against Defendants' FiberCel).

IV. CONCLUSION

For the reasons stated herein, the Court GRANTS Defendants' 12(b)(6) Motion to Dismiss (Dkt. No. 17). Zydek's Counts for negligence (V, X, VX, VI) remain.

IT IS SO ORDERED.

Harry D. Leinenweber, Judge
United States District Court

Dated: 1/18/2024